

**Remarks**

Claims 1-15 are pending in this application. Claims 1-3 are amended herein for clarity and to more particularly describe what applicants consider to be their invention. Support for the amendments to claims 1-3 can be found in claims 1-3 as filed, on page 7, lines 18-21 of the specification and elsewhere throughout the specification. Claims 16-21 are added herein. Support for these new claims can be found in claims 1-15 as filed and on page 9, lines 11-19 of the specification. The Brief Description of the Figures is amended herein to describe Figure 1 as Figures 1A and 1B. Similarly, Figure 2 is amended herein to describe Figures 2A and 2B. No new matter is believed to be added by these amendments. Thus, applicants respectfully request entry of the new claims, reconsideration of this application and allowance of the pending claims to issue.

I. Objection to the Specification

The Office Action states that the disclosure is objected to because the figures contain Figure 1A, 1B, 2A and 2B, while the Description of the Figures merely refers to Figure 1 and Figure 2. The Examiner has suggested that the description of the figures be amended to describe Figure 1A and 1B and Figure 2A and 2B.

As suggested by the Examiner, the Description of the Figures is amended herein to describe Figures 1A, 1B, 2A and 2B. Thus, applicants believe this objection has been overcome and respectfully request its withdrawal.

II. Rejection Under 35 U.S.C. § 112, second paragraph

The Office Action states that claims 1-15 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter with applicant regards as the invention. Specifically, the Office Action states that claims 1-15 are indefinite in the recitation of “fatty acid 13-hydroperoxide lyase” as the specification defines a “fatty acid acid 13-hydroperoxide lyase” as a lyase protein having at least one function exhibited by native 13-hydroperoxide lyase, including catalytic activity as well as antigenic activity. According to the Office Action, the definition of what applicants consider to be encompassed by the term “fatty acid 13-hydroperoxide lyase” is allegedly contrary to that which one of skill in the art would consider to be encompassed by the term. Further stated in the Office Action is that the ordinary artisan would consider a “fatty acid 13-hydroperoxide lyase” to have at the minimum enzymatic or catalytic activity, which as defined by the specification is allegedly not essential for the described protein, only an option.

Applicants agree with the Examiner that one of skill in the art would consider the term “fatty acid 13-hydroperoxide lyase” to encompass enzymatic activity. Thus, when applicants use the term “fatty acid 13-hydroperoxide lyase,” applicants mean that this protein has the enzymatic

function of a native fatty acid 13 hydroperoxide lyase, for example, the catalytic activity of cleaving a fatty acid 13-hydroperoxide into a C-6 aldehyde and a C-12-  $\omega$ -oxoacid moiety. The specification, on page 5, line 28, through page 6, line 6 states that the lyase can have a specific catalytic activity and additionally may have the antigenic determinants of 13-HPOL. Therefore, applicants believe that one of skill in the art would understand the term "fatty acid 13-hydroperoxide lyase" to encompass enzymatic activity, as intended by applicants. Thus, applicants believe the term "fatty acid 13-hydroperoxide lyase" is clear and respectfully request withdrawal of this rejection as it applies to claims 1-15 and new claims 16-21.

III. Rejections Under 35 U.S.C. § 112, first paragraph

A. The Office Action states that claims 1-3 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was allegedly not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office Action further states that claims 1-3 are allegedly directed to all possible methods of cleaving a 13-hydroperoxide or a  $\alpha$ -linolenic acid into C6-aldehyde and a C12-oxocarboxylic acid comprising contacting the 13-hydroperoxide with a recombinant protein comprising any fatty acid lyase comprising the amino acid sequence set forth in SEQ ID NO: 1. Further stated in the Office Action is that the specification only provides the representative species of the claimed methods of use of SEQ ID NOs: 2, 3, 4 and 6, encompassed by the claimed genus. Also stated in the Office Action is that there is allegedly no disclosure of any particular structure to function/activity relationship in the

disclosed species and that the specification allegedly fails to describe additional representative species of the polypeptides necessary for the claimed methods by any identifying structural characteristics of properties for which no predictability of structure is apparent. Thus, the Office concludes that Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

As stated above, when applicants use the term "fatty acid 13-hydroperoxide lyase," applicants mean that this protein has the enzymatic function of a native fatty acid 13 hydroperoxide lyase, for example, the catalytic activity of cleaving a fatty acid 13-hydroperoxide into a C-6 aldehyde and a C-12-  $\omega$ -oxoacid moiety. Thus, applicants are claiming the use of a recombinant protein comprising a fatty acid 13-hydroperoxide lyase that has the enzymatic function of a native fatty acid 13-hydroperoxide lyase. Furthermore, as amended herein, the methods of claims 1-3 utilize "a nucleic acid encoding a fatty acid 13-hydroperoxide lyase comprising the amino acid sequence set forth in SEQ ID NO:1, wherein the amino acid sequence of the recombinant protein is present in a fatty acid 13-hydroperoxide lyase isolated from *Psidium guajava*." Thus, the methods of claims 1-3 encompass the use of an enzymatically functional recombinant fatty acid 13-hydroperoxide lyase comprising the amino acid sequence SEQ ID NO: 1, wherein the amino acid sequence of the recombinant protein is also present in a fatty acid 13-hydroperoxide lyase isolated from *Psidium guajava*. Thus, applicants are not claiming the use of proteins comprising any fatty acid lyase comprising the amino acid sequence

set forth in SEQ ID NO: 1. Applicants instead are claiming recombinant proteins that 1) are enzymatically functional; 2) comprise the amino acid sequence of SEQ ID NO: 1; and 3) have an amino acid sequence that is also present in a fatty acid 13-hydroperoxide lyase isolated from *Psidium guajava*. This narrows the genus encompassed by claims 1-3 considerably, as only those recombinant proteins encoding a fatty acid 13-hydroperoxide lyase that satisfy all three requirements can be utilized in the methods of claims 1-3. Applicants have provided sufficient examples of enzymatically functional fatty acid 13-hydroperoxide lyase amino acid sequences isolated from *Psidium guajava* (SEQ ID NOs: 2, 3, 4 and 6) to show that applicants were in possession of the methods set forth in claims 1-3.

Futhermore, applicants respectfully point out to the Examiner that a nucleic acid encoding a protein comprising a fatty acid 13-hydroperoxide lyase, wherein the lyase comprises the amino acid sequences set forth in SEQ ID NO: 1 and wherein the amino acid sequence is present in a fatty acid 13-hydroperoxide lyase isolated from *Psidium gauajava* was found to be patentable in U.S. Patent No. 6,200,794 B1. Therefore, a method of utilizing the nucleic acid patented in U.S. Patent No. 6,200,794 B1 should also be patentable. Thus, based on the teachings of the specification and the patented subject matter of U.S. Patent No. 6,200,794 B1, it would be clear to one of skill in the art that the inventors were in possession of the claimed invention.

B. The Office Action states that claims 1-3 are rejected under 35 U.S.C. §112, first paragraph, because the specification while being enabling for those claimed methods of use of a 13-hydroperoxide lyase enzyme wherein said polypeptide comprises the amino acid sequence of SEQ ID NOs 2, 3, 4 or 6, allegedly does not reasonably provide enablement for those claimed methods of use of a 13-hydroperoxide lyase enzyme wherein said polypeptide merely comprises SEQ ID NO: 1. The Office sets forth the Wands factors and concludes that applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any 13-hydroperoxide lyase, so long as the polypeptide comprises SEQ ID NO: 1.

As stated above, the genus of proteins that can be utilized in the methods of the present invention does not include all of the recombinant fatty acid 13-hydroperoxide lyases that comprise SEQ ID NO: 1, but rather recombinant fatty acid 13-hydroperoxide lyases that 1) are enzymatically functional; 2) comprise SEQ ID NO: 1; and 3) have an the amino acid sequence that is also present in a fatty acid 13-hydroperoxide lyase isolated from *Psidium guajava*. Applicants have provided several examples of naturally occurring fatty acid 13-hydroperoxide lyase sequences, such that one of skill in the art could modify these sequences or others isolated from *Psidium guajava* to practice the methods as claimed.

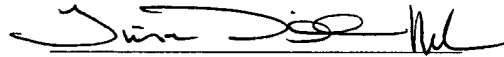
Furthermore, as stated above, a nucleic acid comprising a nucleic acid encoding a protein comprising a fatty acid 13-hydroperoxide lyase, wherein the lyase comprises the amino acid sequences set forth in SEQ ID NO: 1 and wherein the amino acid sequence is present in a fatty acid 13-hydroperoxide lyase isolated from *Psidium guajava* was found to be patentable in U.S. Patent No. 6,200,794 B1. Therefore, a method of utilizing the nucleic acid patented in U.S. Patent No. 6,200,794 B1 should also be patentable. Thus, based on the teachings of the specification and the patented subject matter of U.S. Patent No. 6,200,794 B1, it would be clear to one of skill in the art that the methods of claims 1-3 are adequately enabled. Thus, applicants believe this rejection has been overcome and respectfully request its withdrawal.

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$416.00 (\$306.00 for additional claims (3 independent claims and 3 dependent claims) and \$110.00 for a one-month extension of time) is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

ATTORNEY DOCKET NO. 06027.0001U3  
Application No. 10/042,991

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.



Tina W. McKeon  
Registration No. 43,791

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859  
(678) 420-9300  
(678) 420-9301 (fax)

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.



Tina W. McKeon

September 8, 2003

Date